

CLAIMS

1. A method of diagnosing bone metastasis of malignant tumor using a marker that reflects the activity of osteoblasts and a marker that reflects the action of osteoclasts.

2. The method according to claim 1, wherein the marker that reflects the activity of osteoblasts is:

(1) a marker associated with the phase of osteoblast proliferation and matrix formation and a marker associated with the phase of calcification; or  
(2) a marker associated with the phase of matrix maturation and a marker associated with the phase of calcification.

3. The method according to claim 1 or 2, wherein the marker that reflects the activity of osteoblasts is:

(1) PICP or PINP and osteocalcin; or  
(2) BALP and osteocalcin.

4. The method according to any one of claims 1 - 3, wherein the marker that reflects the action of osteoclasts is a marker associated with bone type I collagen.

5. The method according to any one of claims 1 - 4,

wherein the marker that reflects the action of osteoclasts is deoxypyridinoline and/or ICTP.

6. The method according to any one of claims 1 - 5,

which is based on the value of a crossover index or the ratio between a marker associated with the phase of calcification and a marker associated with the phase of osteoblast proliferation and matrix formation and the measured value of the marker that reflects the action of

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osteoclasts, or on the value of a crossover index or the ratio between a marker associated with the phase of calcification and a marker associated with the phase of matrix maturation and the measured value of a marker associated with bone type I collagen.

7. The method according to claim 6, which is based on the value of a crossover index between osteocalcin and PICP or PINP and the measured value of ICTP, or on the value of a crossover index between osteocalcin and BALP and the measured value of ICTP.

8. A method of evaluating the therapeutic efficacy of a drug using a marker that reflects the activity of osteoblasts and a marker that reflects the action of osteoclasts.

9. The method according to claim 8, wherein the drug is a cancer control therapeutic agent.

10. The method according to claim 8, wherein the drug is a bone resorption suppressant.

11. The method according to claim 8, wherein the drug is an endocrine therapeutic agent.

12. The method according to any one of claims 8 - 11, wherein the marker that reflects the activity of osteoblasts is:

(1) a marker associated with the phase of osteoblast proliferation and matrix formation and a marker associated with the phase of calcification; or

(2) a marker associated with the phase of matrix maturation and a marker associated with the phase of calcification.

*claim 8*

*a* *Claim 8*

13. The method according to any one of claims 8 or 12,

wherein the marker that reflects the activity of osteoblasts is:

(1) PICP or PINP and osteocalcin; or

(2) BALP and osteocalcin.

*a* *Claim 8*

14. The method according to any one of claims 8 - 13,

wherein the marker that reflects the action of osteoclasts is a marker associated with bone type I collagen.

15. The method according to any one of claims 8 - 14, *Claim 8*

wherein the marker that reflects the action of osteoclasts is deoxypyridinoline and/or ICTP. *Claim 8*

16. The method according to any one of claims 8 - 15,

which is based on the value of a crossover index or the ratio between a marker associated with the phase of calcification and a marker associated with the phase of osteoblast proliferation and matrix formation and the measured value of the marker that reflects the action of osteoclasts, or on the value of a crossover index or the ratio between a marker associated with the phase of calcification and a marker associated with the phase of matrix maturation and the measured value of a marker associated with bone type I collagen.

17. The method according to claim 16, which is based on

the value of a crossover index between osteocalcin and PICP or PINP and the measured value of ICTP, or on the value of a crossover index between osteocalcin and BALP and the measured value of ICTP.

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